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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/617,334	HAYDEN ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27,29-40 and 46-66* is/are pending in the application.

4a) Of the above claim(s) *1-23,29-40,46-48 and 50-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-27,49 and 57-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/22/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/22/07 has been entered.

[2] Claims 1-27, 29-40, and 46-66 are pending in the application.

[3] Applicant's amendment to the claims, filed on 8/22/07, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[4] Receipt of terminal disclaimers, filed on 8/22/07, is acknowledged.

[5] Receipt of an information disclosure statement, filed on 8/22/07, is acknowledged.

[6] Applicant's arguments filed on 8/22/07 in response to the Office action mailed on 2/22/07 have been fully considered and are deemed to be persuasive to overcome some of the objections and/or rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[7] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Election/Restriction

[8] Claims 1-23, 29-40, 46-48, and 50-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/6/2006.

[9] Claims 49, 58, and 60 are being examined only to the extent the claims read on the elected subject matter.

Information Disclosure Statement

[10] All references cited in the information disclosure statement filed on 8/22/07 have been considered by the examiner. A copy of Form PTO-1449 is attached to the instant Office action.

Claim Objection

[11] Applicant is advised that should claim 61 be found allowable, claim 62 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112, Second Paragraph

[12] Claim(s) 24-27, 49, and 57-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is drawn to a method for treating a human, wherein the treatment is achieved by "increasing by at least 10% the level of ABC1 lipid transport..." While it is clear how the treatment is effected, *i.e.,* by "increasing...the level of ABC1 lipid transport activity," there is no recitation of an active method step or steps to arrive at this effect. Since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. Claim 24 (claims 25-27, 49, and 57-66 dependent therefrom) is indefinite because it fails to recite any active, positive steps delimiting how the treatment method is actually practiced. See particularly MPEP 2173.05(q).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[13] Claims 24-27, 49, and 57-66 are rejected under 35 U.S.C. 101 because a method claim, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App.

1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See also MPEP 2173.05(q).

Claim Rejections - 35 USC § 112, First Paragraph

[14] Claims 24-27, 49, and 57-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

According to MPEP 2163.II.A.1, in evaluating a claimed invention for adequate written description, the examiner should determine what the claim as a whole covers. "Claim construction is an essential part of the examination process. Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description. See, e.g., *In re Morris*, 127 F.3d 1048, 1053-54, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997)."

Claim 24 is drawn to a genus of methods of treating a human having or at risk of developing a cardiovascular disease to increase plasma HDL-C in said human by increasing by at least 10% the level of ABC1 lipid transport activity in said human. It is noted that while the method is drawn to "treating a human having or at risk of developing a cardiovascular disease," what is actually treated "by increasing...ABC1 lipid transport activity" is undefined and unlimited in the claims. In this case, the

recitation of "human having or at risk of developing a cardiovascular disease" merely defines the population of those that are treated without specifying *what* is treated. As such, the claims encompass methods for any treatment including, *e.g.,* methods for treating any disease or disorder in the affected humans as defined by the claims. The method is unlimited with respect to how the ABC1 lipid transport activity is increased. As such, the claim is interpreted herein as encompassing any method or mechanism by which ABC1 lipid transport activity is increased by 10%, 25%, or 50%.

For claims drawn to a genus, MPEP § 2163 states the written description requirement for a genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Sufficient description to show possession of such a genus "may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. *See University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895. MPEP § 2163 states that a representative

number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

As noted above, the genus of claimed methods encompasses widely variant species, encompassing any method or mechanism by which ABC1 lipid transport activity is increased by 10%, 25%, or 50%. However, the specification fails to disclose even a single representative species of methods by which ABC1 lipid transport activity is increased by 10%, 25%, or 50% in a human as defined by the claims. As noted in the prior Office action, even after the time of the invention, there is a high level of unpredictability regarding those treatment methods targeting ABCA1 as evidenced by the teachings of the reference of Nofer et al., which discloses that a therapeutic for targeting ABCA1 in the treatment of coronary heart disease "has not yet been fulfilled" (Nofer et al. *Cell Mol Life Sci* 62:2150-2160, 2005; p. 2156, right column, bottom). According to MPEP 2163.II.3.(a).ii), "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus." *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004). Since the specification and prior art fail to

disclose even a single representative species of the claimed genus of methods and because there is unpredictability in the art of treating coronary heart disease via ABCA1, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

RESPONSE TO ARGUMENT: Beginning at p. 11, middle of the instant remarks, applicant argues *Rochester* does not apply here because in this case, applicant has disclosed a compound that increases ABC1 lipid transport activity, *i.e.,* the ABC1 polypeptide itself. According to applicant, numerous species of ABC1 polypeptides are disclosed in the application, which is sufficient to show possession of the claimed invention.

Applicant's argument is not found persuasive. It is noted that the claimed treatment method is not limited to administering an ABC1 polypeptide that is disclosed in the specification. Instead, as noted above, the claims are unlimited with respect to how the ABC1 lipid transport activity is increased, including administering any compound having any structure (*e.g.*, small molecule organics, nucleic acids, and polypeptides including antibodies) that effects an increase in ABC1 lipid transport activity. Even if the claims were limited to administering an ABC1 polypeptide (that is adequately described in the specification), it is noted that the specification fails to provide evidence that applicant was in possession of a method whereby a human can be treated for any disease or disorder by administering an ABC1 polypeptide to increase ABC1 lipid transport activity by at least 10%, 25%, or 50% in the affected

human. Thus, at least for the reasons set forth above, it is the examiner's position that the specification fails to adequately describe the claimed invention.

[15] Claims 24-27, 49, and 57-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

MPEP § 2163.II.A.3.(b) states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description."

According to applicant (instant remarks at p. 15, top), support for the limitation of "increasing by at least 10% the level of ABC1 lipid transport activity", including at least 25% or 50% (claims 24 and 63-64) or the limitation of "plasma HDL-C is increased by at least 25%", including at least 50% (claims 65-66) can be found at p. 14, lines 18-22 of the specification. The cited disclosure states, "By 'modulates' is meant increase or decrease. Preferably, a compound that modulates cholesterol levels (e.g., HDL-cholesterol levels, LDL-cholesterol levels, or total cholesterol levels), or ABC1 biological

activity, expression, stability, or degradation does so by at least 10%, more preferably by at least 25%, and most preferably by at least 50%." This disclosure appears to be related to providing descriptive support for a "compound" that modifies cholesterol or ABC1 activity by at least 10%, more preferably by at least 25%, and most preferably by at least 50%. However, as noted above, claim 24 is not limited to treatment by administering a compound. Instead, the method or mechanism by which the ABC1 lipid transport activity is increased is unlimited and has been broadly but reasonably interpreted accordingly. As such, the disclosure at p. 14, lines 18-22 would not appear to provide explicit, implicit, or inherent disclosure to support the noted limitations. Applicant is invited to show support for the limitations of new claims 57-62.

[16] Claims 24-27, 49, and 57-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue." *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). It is the examiner's position that undue experimentation would be required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8

USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

(A) The breadth of the claims: According to MPEP 2164.04, "[b]efore any analysis of enablement can occur, it is necessary for the examiner to construe the claims...and explicitly set forth the scope of the claim when writing an Office action." Also, MPEP 2164.08 states, "[a]ll questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim is enabled. Accordingly, the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims...claims are to be given their broadest reasonable interpretation that is consistent with the specification."

As noted above, the claims are drawn to a method of treating a human having or at risk of developing a cardiovascular disease to increase plasma HDL-C in said human by increasing by at least 10%, 25% or 50% the level of ABC1 lipid transport activity in said human. It is noted that while the method is drawn to "treating a human having or at risk of developing a cardiovascular disease," what is actually treated "by increasing...ABC1 lipid transport activity" is undefined and unlimited in the claims. In

this case, the recitation of "human having or at risk of developing a cardiovascular disease" merely defines the population of those that are treated without specifying *what* is treated. As such, the claims encompass methods for any treatment including, *e.g.*, methods for treating any disease or disorder in the affected humans as defined by the claims. Also, as noted above, the method is unlimited with respect to *how* the ABC1 lipid transport activity is increased, broadly encompassing methods of gene therapy and/or administering any compound(s) that achieve the desired increase of 10%, 25%, or 50% of ABCA1 lipid transport activity.

(C) The state of the prior art; (D) The level of one of ordinary skill; and (E) The level of predictability in the art: According to MPEP 2164.03, "...what is known in the art provides evidence as to the question of predictability." At the time of the invention, neither the specification nor the prior art discloses a method for providing any treatment in a human having or at risk of developing a cardiovascular disease by increasing by at least 10%, 25%, or 50% the level of ABC1 lipid transport activity in the human. Even *after* the time of the invention the art recognizes that a therapeutic targeting ABCA1 for the treatment of coronary heart disease "has not yet been fulfilled" (Nofer et al. *Cell Mol Life Sci* 62:2150-2160, 2005; p. 2156, right column, bottom), providing evidence of a high level of unpredictability for practicing the claimed method. While Nofer et al. acknowledges that "such treatments may be on the horizon," the reference also acknowledges that at least one potential therapy, namely LXR agonists, may cause gene changes that are detrimental (p. 2157, left column, top). In this case, the specification and/or prior art fail to set forth even a single method for achieving an

increase in ABC1 lipid transport activity of at least 10% to provide a treatment to a human.

(F) The amount of direction provided by the inventor and (G) The existence of working examples: The specification fails to disclose even a single working example of the claimed method that achieves an increase of at least 10% of ABC1 lipid transport activity in an affected human as encompassed by the claims. While it is acknowledged that MPEP 2164.02 states, "[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed," this same section of MPEP makes clear that "[l]ack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art." While the specification discloses general methods for, *e.g.,* isolating compounds that may achieve the desired increase in ABCA1 lipid transport activity, such guidance amounts to a trial and error research plan without providing any specific guidance regarding those compounds that are likely to be successful for practicing the claimed method. The specification fails to provide guidance regarding, *e.g.,* production of the polypeptide and the associated potential for antigenic effects in a human, whether or not the polypeptide has lipid transport activity without further processing or post-translational modification, stability/turnover of the polypeptide, formulation of the polypeptide for administration, routes of administration, and dosage level required to achieve increased ABC1 lipid transport activity by at least 10%, 25%, or 50% in a human, which are all relevant considerations for protein therapeutics. In this case, in view of the high level of unpredictability and lack of guidance provided in the

specification, a skilled artisan would have no expectation that such a method can be achieved.

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: While methods of treatment of a cardiovascular disease were known in the art at the time of the invention, it was not routine to experiment to identify a method for increasing by at least 10%, 25%, or 50% the ABCA1 lipid transport activity in a human.

In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation would be necessary for a skilled artisan to make and use the claimed invention.

RESPONSE TO ARGUMENT: Beginning at p. 13, bottom of the instant remarks, applicant argues: 1) claim 24 has been amended to recite increasing ABC1 lipid transport activity as the basis for treatment rather than administering any specific agents; 2) applicant should be entitled to the full breadth of the claim because the parent application, which issued as US Patent 6,617,122, discloses the role of ABCA1 in human health and is a "pioneering patent"; 3) drug development is routine; and 4) applicant has disclosed ABC1 polypeptides and fragments thereof that are useful in increasing ABCA1 lipid transport activity and therefore should not be limited to specific examples.

Applicant's argument is not found persuasive. Applicant's amendment to claim 24 is acknowledged. It is noted that the claimed treatment method is not limited to

administering an ABC1 polypeptide or fragments thereof. Instead, as noted above, the claims are unlimited with respect to how the ABC1 lipid transport activity is increased by at least 10% in a human, including administering any compound having any structure (*e.g.*, small molecule organics, nucleic acids, and polypeptides including antibodies) that effects an increase in ABC1 lipid transport activity. Even if the claims were limited to administering an ABC1 polypeptide that is expressly disclosed in the specification, it is noted that there is no evidence of record and a skilled artisan would have no expectation that administering such polypeptide would have the required activity of increasing ABC1 lipid transport activity by at least 10%, 25%, or 50% in the affected human as encompassed by the claims. In this case, the specification fails to provide even a single working example of the claimed method even in an animal model to suggest that administering an ABCA1 polypeptide can achieve the desired increase in ABC1 lipid transport activity by at least 10%, 25%, or 50%. The specification fails to provide guidance regarding, *e.g.,* production of the polypeptide and the associated potential for antigenic effects in a human, whether or not the polypeptide has lipid transport activity without further processing or post-translational modification, stability/turnover of the polypeptide, formulation of the polypeptide for administration, routes of administration, and dosage level required to achieve increased ABC1 lipid transport activity by at least 10%, 25%, or 50% in a human, which are all relevant considerations for protein therapeutics. Thus, at least for the reasons set forth above, it is the examiner's position that the specification fails to enable the claimed invention.

Claim Rejections - 35 USC § 102

[17] 1) The rejection of claim(s) 24-27, 42, 49, and 59-60 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Smud et al. as evidenced by Steiner et al. and Arakawa et al. is withdrawn; 2) the rejection of claim(s) 24-27, 42, 49, and 57-62 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hahmann et al. as evidenced by Arakawa et al. is withdrawn; and 3) the rejection of claim(s) 24-27, 41, 49, and 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Olivier et al. as evidenced by Mack et al. and Arakawa et al. is withdrawn. The rejection based on the reference of Olivier et al. is withdrawn as the method of Olivier administers a compound to mice – not humans as required by claim 24. Also, the rejection based on the references of Smud et al. or Hahmann et al. is withdrawn as the examiner, while previously providing evidence that by practicing the method of Smud et al. or Hahmann et al. the level of ABCA1 mRNA and protein is increased, can find no evidence that such method results in an increase by at least 10% the level of ABC1 lipid transport activity in a human as required by claim 24. As noted in MPEP 2112.IV, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic...'To establish inherency, the extrinsic evidence must

make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary

skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'"

Claim Rejections - Double Patenting

[18] 1) The provisional obviousness-type double patenting rejection of claims 24-28, 41-45, 49, and 57-62 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-24 and 26-27 of co-pending US non-provisional application 10/479,198; 2) the provisional obviousness-type double patenting rejection of claims 24-28, 41-45, 49, and 57-62 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-28 and 32 of co-pending US non-provisional application 10/745,377; 3) and the provisional obviousness-type double patenting rejection of claims 24-28, 41-45, 49, and 57-62 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-48 of co-pending US non-provisional application 10/833,679 are withdrawn in view of applicant's submission of a terminal disclaimer addressing each of the co-pending applications noted above.

[19] Applicant is reminded that the examiner has made an earnest attempt to identify those patents and/or co-pending applications for purposes of rejecting or provisionally rejecting the claims for double patenting. However, it is noted that numerous co-pending applications have been filed and/or continue to be filed, and/or patents have issued disclosing subject matter that is related to the instant application. In the interest of

compact prosecution, the examiner requests that: 1) applicants identify any patent(s) and/or co-pending application(s) that claim(s) subject matter that may necessitate a double patenting rejection, an obviousness-type double patenting rejection, a provisional double patenting rejection, or a provisional obviousness-type double patenting rejection; 2) identify the claims of the patents and/or co-pending applications that claim identical or similar subject matter; 3) identify the corresponding claims of the instant application, and 4) take the appropriate action, *e.g.,* cancel claims to preempt a statutory double patenting rejection and/or file a terminal disclaimer to preempt an obvious-type double patenting rejection or provisional rejection. Applicants' cooperation in following steps 1) to 4) above is appreciated as this will allow the examiner to focus on more substantive issues in the examination of the instant application.

Conclusion

[20] Status of the claims:

- Claims 1-27, 29-40, and 46-66 are pending.
- Claims 1-23, 29-40, 46-48, and 50-56 are withdrawn from consideration.
- Claims 24-27, 49, and 57-66 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656